

### REMARKS

Claim 3 has been amended to depend from claim 4 instead of claim 1. No new matter has been added. Claims 2-4, 7-10, 12, 14-16, 19-23, and 27-29 are currently pending for examination.

#### Claim Objections

Claim 3 has been objected to for depending on cancelled claim 1. This has been corrected.

#### Rejections under 35 U.S.C. §103(a)

Claims 3, 4, 7-10, 12, 14, 15, 19-23, and 27-29 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Fossel, U.S. Pat. Apl. Pub. No. 2003/0028169 ("Fossel") in view of Falk, *et al.*, U.S. Pat. No. 5,824,658 ("Falk"). The Patent Office states that Fossel discloses applying a delivery vehicle to a selected area of the skin, and Falk teaches a method of treating the skin of the breast by rubbing a gel or cream into the skin. The Patent Office then states that it would have been obvious to include, in the method of Fossel, a step of rubbing the cream into the breast, as taught by Falk, in order to improve the therapeutic effect of the treatment.

Falk is specifically directed to systems and methods of treating pain topically using a pharmaceutical composition that comprises an NSAID, and hyaluronic acid. See, for example, the Title and Abstract of Falk. Falk does not teach that one of ordinary in the art would apply a cream to the breast merely to improve any "therapeutic effect," as alleged by the Patent Office, but instead Falk only teaches applying an NSAID and hyaluronic acid to a disease or condition on exposed skin. The passages in Falk alleged by the Patent Office for teaching improving a "therapeutic effect" are shown below (col. 12, line 1, lines 12-15, and line 16), and clearly are directed to treatments involving an NSAID and hyaluronic acid. Rather than taking words out of their proper context, as the Office Action appears to have done, the *entire* paragraph containing col. 12, line 1, lines 12-15, and line 16 is reproduced below, with the bolded passages being the ones referred to in the Office Action:

Thus, according to another aspect of the invention, a method of treating a disease and/or condition of the skin or exposed tissue, for example basal cell carcinoma, the precancerous, often recurrent, actinic keratoses lesions, fungal lesions, "liver" spots and like lesions (found

for the most part in the epidermis), squamous cell tumours, metastatic **cancer of the breast to the skin, primary and metastatic** melanoma in the skin, malignancies and/or tumours in the skin, genital warts (condyloma acuminata), cervical cancer, HPV (Human Papilloma Virus) including HPV of the cervix, psoriasis (both plaque-type psoriasis and nail bed psoriasis), corns on the feet and hair loss on the head of pregnant women, in a human is provided comprising administering topically to human skin and/or exposed tissue an effective non-toxic dosage amount of a composition comprising, together with pharmaceutical excipients suitable for topical application to the skin and/or exposed tissue, for example **in the form of a gel or cream (to give the composition definition and form so that specific dosage amounts are easily selected or taken for administration (for example squeezed from a tube or scooped from a jar and rubbed into the skin or exposed tissue), a therapeutically effective (to treat and to assist to** resolve the disease or condition for example basal cell carcinoma or other lesion), non-toxic (to the patient) dosage amount of a drug for example which inhibits prostaglandin synthesis, for example a non-steroidal anti-inflammatory drug (NSAID), for example, diclofenac, indomethacin, naproxen, and (+) tromethamine salt of ketorolac (sold under the trademark Toradol™) and an effective non-toxic dosage amount of hyaluronic acid and/or salts thereof (for example, the sodium salt) and/or homologues, analogues, derivatives, complexes, esters, fragments, and/or sub-units of hyaluronic acid (preferably hyaluronic acid and salts thereof) to transport (facilitate or cause the transport of) the drug (for example NSAID) into the skin or exposed tissue to the site of the disease or condition to be treated percutaneously, (to the site of trauma and/or pathology), for example into the epidermis, where the form of hyaluronic acid and medicine accumulates and remains for a prolonged period of time thereby for example blocking prostaglandin synthesis in the skin or exposed tissue. [Emphasis added.]

The bolded passages above do not teach or suggest to one of ordinary skill in the art to apply a cream to the breast for any purpose whatsoever, but instead recite that the cream is applied to a region of the skin—not necessarily the breast—to treat cancers such as metastatic cancer of the breast to the skin, or metastatic melanoma (col. 12, line 1). In particular, it should be noted that Falk does not teach applying a cream to the breast, but instead teaches applying a cream to a portion of the skin where there is cancer that has *metastasized from the breast*. This is the ordinary meaning of “metastatic cancer of the breast to the skin,” and is consistent with what is scientifically known about how metastatic cancers spread through the body (i.e., by transport through the bloodstream, not via “diffusion” from the breast tissue to the skin immediately surrounding the breast tissue). Accordingly, Falk nowhere teaches or suggests applying a cream to the breast.

In addition, although the formulation taught in Falk is in the form of a gel or cream, the above passage from Falk states that a “therapeutically effective” amount is an amount used to treat the aforementioned conditions (i.e., cancers such as metastatic cancer of the breast to the skin, or

metastatic melanoma). The bolded passages in Falk cannot reasonably be interpreted to mean otherwise. Accordingly, one of ordinary skill in the art would understand Falk to be a method of applying an NSAID and hyaluronic acid to the skin to treat cancers, including cancers that have metastasized from breast cancers, and one of ordinary skill in the art would not understand Falk to teach or suggest applying a cream to the breast.

Fossel, on the other hand, nowhere discloses or suggests applying a delivery vehicle into the breast, as acknowledged by the Patent Office. Fossel is generally directed to producing beneficial effects such as growth of hair on the scalp, healing of leg ulcers secondary to diabetes or confinement to bed and overcoming erectile dysfunction, as well as beneficial effects through restoration of natural mechanisms based on improvement of local blood supply (see paragraph [0003] of Fossel). There is no discussion in Fossel of applying such a delivery vehicle to the breast, nor is it seen why one of ordinary skill in the art would have any rational reason to modify Fossel in such a fashion, especially when there is generally no desire to grow hair on the breast, there are no leg ulcers typically found on the breast, treatment of erectile dysfunction would seem to be of no importance to the breast (especially since that would implicate treatment of the *wrong* sex), and the breasts do not generally contain a rich supply of blood vessels that would warrant treatment by restoration of natural mechanisms therein. In short, the Patent Office has set forth no plausible mechanism or articulate reasoning by which one of ordinary skill in the art would attempt to modify Fossel in order to apply the delivery vehicle of Fossel to the breast.

Since neither Falk nor Fossel recites applying a cream to the breast, no combination of Falk and Fossel, to the extent these references can be combined (which is not conceded), would teach or fairly suggest to one of ordinary skill in the art to apply a cream to the breast. Thus, the combination of Falk and Fossel is improper, and it is respectfully requested that this rejection be withdrawn.

#### Rejections under 35 U.S.C. §103(a)

Claim 2 has been rejected under 35 U.S.C. §103(a) as being unpatentable over Fossel in view of Falk, and further in view of Nakata, *et al.*, U.S. Pat. No. 5,332,758 (“Nakata”).

Claims 2 depends from claim 4. For at least the reasons explained above with respect to the rejection under §103(a) in view of the combination of Fossel and Falk, the premise of the rejection of claim 4 (that Fossel and Falk could be combined to render claim 4 obvious) is believed to be incorrect. Accordingly, while Applicant does not concede that there would have been any rational reason to combine Fossel, Falk, and Nakata in the manner suggested in the Office Action, the present rejection cannot stand. Thus, withdrawal of the rejection of claim 2 is respectfully requested.

#### Rejections under 35 U.S.C. §103(a)

Claim 16 has been rejected under 35 U.S.C. §103(a) as being unpatentable over Fossel in view of Falk, and further in view of Marty, U.S. Pat. No. 4,702,913 ("Marty").

Claims 16 is dependent on claim 4. For at least the reasons discussed above regarding the rejection under §103(a) in view of the combination of Fossel and Falk, the premise of the rejection of claim 4 (that Fossel and Falk could be combined to render claim 4 obvious) is believed to not be correct. Thus, while it is not conceded that there would have been any rational reason to combine Fossel, Falk, and Marty in the manner suggested by the Patent Office, the present rejection cannot stand. Accordingly, it is respectfully requested that this rejection be withdrawn.

#### CONCLUSION

Favorable action is respectfully requested. If, for any reason, the Examiner is of the opinion that a telephone conversation with the Applicant's representative would expedite prosecution, the Examiner is kindly invited to contact the undersigned at the number below.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicant hereby requests any necessary extension of time. Please charge any fee or fee deficiency occasioned by this Response that is not covered by an enclosed check to Deposit Account No. 23/2825 under Docket No. S1509.70037US01 from which the undersigned is authorized to draw.

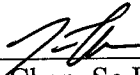
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